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New Atty. Dkt. No. 034536-0155 Old Atty. Dkt. No. 038602-1060

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Narmada SHENOY et al.

Title:

FORMULATIONS FOR PHARMACEUTICAL AGENTS

IONIZABLE AS FREE ACIDS OR FREE BASES

Appl. No.:

09/716,332

Patent No.:

6,878,733 B1

Filing Date:

November 21, 2000

Examiner:

Dwayne C. Jones

Art Unit:

1614

Grant Date:

April 12, 2005

REQUEST FOR RECONSIDERATION OF PATENT TERM ADJUSTMENT UNDER 37 CFR §1.705

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Sir:

Applicants respectfully request reconsideration of the Decision On Request For Reconsideration of Patent Term Adjustment mailed January 23, 2006, in connection with the captioned patent, U.S. Patent No. 6,878,733. This Request for Reconsideration is timely submitted within two months of the mailing date of the Decision.

The Decision states that the Patent Term Adjustment of 295 days accorded when the patent issued is correct. However, Applicants have determined that this adjustment is based on an erroneous deduction of 120 days due to applicant delay that did not occur. Calculating the Patent Term Adjustment without the erroneous 120 day deduction results in an adjustment of 415 days, as requested in Applicants' previous Request For Reconsideration of Patent Term Adjustment.

The Patent Term Adjustment information available to the Petitions Attorney on PALM (a copy of which was provided to Applicants as a courtesy, and is attached as Exhibit A) and the information publicly available on PAIR (copy attached as Exhibit B) indicate that the accorded 295 days is based on the following calculations:

Days of Patent Office Delay:

10 days of delay under Rule 703(a)(1)

262 days of delay under Rule 703(a)(6)

236 days of delay under Rule 703(b), as adjusted for overlap with delay under Rule 703(a)

Total Days of Patent Office Delay = 508 days

Days of Applicant Delay

91 days of delay in submitting response filed December 6, 2002

2 days of delay in submitting response filed October 20, 2003

120 days of delay in submitting: "Amendment After Notice Of Allowance," on March 24, 2004

Total Days of Applicant Delay = 213 days

Patent Term Adjustment = 508 days - 213 days = 295 days

Applicants note, however, that the 120 days of Applicant delay highlighted above is erroneous. Applicants did not submit any Amendment After Notice of Allowance. The only submissions made on March 24, 2004 were (i) the Issue Fee transmittal, (ii) copies of PTO Form PTOL-85 (Issue Fee transmittals), (iii) the Issue Fee payment check, (iv) the initial Request for Reconsideration of Patent Term Adjustment, and (v) a check for the Request for Reconsideration fee. A copy of Applicants' receipt postcard for these submissions, listing only these items and stamped by the Patent Office on March 24, 2004, is attached as Exhibit C.

The listing of documents under the "Image File Wrapper" tab for this patent on PAIR (copy attached as Exhibit D) corresponds to Applicants' records. The listing shows the following items for March 24, 2004:

- (1) Petition for review and processing by the Office of Petitions (this is the Request for Reconsideration of Patent Term Adjustment)
- (2) Issue Fee Payment Recorded

The listing of documents under the "Transaction History" tab for this patent on PAIR (copy attached as Exhibit E) does not show the Petition (Request for Reconsideration) filed March 24, 2004, but instead erroneously lists an "Amendment After Notice of Allowance (Rule 312)" as being filed on that date. This appears to be the source of the error in the Patent Office's Patent Term Adjustment calculation.

Because Applicants did not submit an "Amendment After Notice of Allowance (Rule 312)" on March 24, 2004, the assessment of 120 days of delay against Applicants for such a submission is improper. Instead, the period of Patent Term Adjustment for the patent should be calculated as follows:

Days of Patent Office Delay:

10 days of delay under Rule 703(a)(1)

262 days of delay under Rule 703(a)(6)

236 days of delay under Rule 703(b), adjusted for overlap with delay under Rule 703(a)

Total Days of Patent Office Delay = 508 days

Days of Applicant Delay

91 days of delay in submitting response filed December 6, 2002

2 days of delay in submitting response filed October 20, 2003

New Atty. Dkt. No. 034536-0155 Old Atty. Dkt. No. 038602-1060

Total Days of Applicant Delay = 93 days

W/st.

002**1**(377)

Patent Term Adjustment = $508 \text{ days} - 93 \text{ days} = \underline{415 \text{ days}}$

In view of the foregoing, Applicants respectfully request reconsideration of the Decision on Patent Term Adjustment, and an award of a Patent Term Adjustment of 415 days for the captioned patent.

The Patent Office has acknowledged receipt of the \$200.00 fee required by 37 CFR § 1.18(e), filed with the original Request for Reconsideration. Therefore, no additional fees are required. However, the Commissioner is authorized to charge any fees due to Deposit Account No. 19-0741.

If there are any questions regarding this submission, or if any issues remain, the Patent Office is invited to contact the undersigned attorney of record at the telephone number set forth below.

Respectfully submitted,

Date 2 27 06

FOLEY & LARDNER LLP

Customer Number: 22428

Telephone:

(202) 672-5475

Facsimile: (20

(202) 672-5399

Beth A. Burrous Attorney for Applicant

Registration No. 35,087

02/

Beth Burrows

202-672-5399

Day: Thursday Date: 2/16/2006

Time: 11:13:10

PALM INTRANET

PTA Calc	ulations for Applic	cation: <u>09/716332</u>	
Application Filing Date:	11/21/2000	PTO Delay (PTO):	508
Issue Date of Patent:	04/12/2005	Three Years:	0
Pre-Issue Petitions:	0	Applicant Delay (APPL):	213
Post-Issue Petitions:	0	Total PTA (days):	295
PTO Delay Adjustment:	0		

		File Contents History			
Number	Date	Contents Description	PTO	APPL	START
48.5	03/23/2005	PTA 36 MONTHS	236		
48		PATENT ISSUE DATE USED IN PTA CALCULATION	262		43
47	02/17/2005	RECEIPT INTO PUBS			
46	02/17/2005	DISPATCH TO FDC			
45	02/17/2005	APPLICATION IS CONSIDERED READY FOR ISSUE			
44	02/17/2005	RESPONSE TO AMENDMENT UNDER RULE 312			
43	03/24/2004	ISSUE FEE PAYMENT VERIFIED			
42	02/08/2005	PETITION DECISION - DISMISSED			
41	03/24/2004	PETITION ENTERED			
40	03/24/2004	AMENDMENT AFTER NOTICE OF ALLOWANCE (RULE 312)		120	
38	06/10/2004	RECEIPT INTO PUBS			
37	03/24/2004	ISSUE FEE PAYMENT RECEIVED			
36	03/22/2004	RECEIPT INTO PUBS			
35	03/19/2004	WORKFLOW - FILE SENT TO CONTRACTOR][]		
34	12/24/2003	MAIL NOTICE OF ALLOWANCE			
33	12/24/2003	MAIL EXAMINER'S AMENDMENT	<u> </u>		
32	12/20/2003	ISSUE REVISION COMPLETED			
31	12/22/2003	NOTICE OF ALLOWANCE DATA VERIFICATION COMPLETED			
30	12/22/2003	CASE DOCKETED TO EXAMINER IN GAU			
29	12/22/2003	EXAMINER'S AMENDMENT COMMUNICATION			
28	12/22/2003	NOTICE OF ALLOWABILITY			
27	11/07/2003	IFW AMENDED CASE PROCESSING COMPLETE			
26	11/07/2003	DATE FORWARDED TO EXAMINER			

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25	10/20/2003	RESPONSE AFTER NON-FINAL ACTION		2	24
24	07/18/2003	MAIL NON-FINAL REJECTION			
23	07/18/2003	NON-FINAL REJECTION			
22	07/10/2003	DATE FORWARDED TO EXAMINER			
21	06/19/2003	AMENDMENT AFTER FINAL REJECTION			
20	03/19/2003	MAIL FINAL REJECTION (PTOL - 326)			
19	03/19/2003	FINAL REJECTION			
18		DATE FORWARDED TO EXAMINER			
17	12/06/2002	RESPONSE AFTER NON-FINAL ACTION	igsquare	91	15
16	12/06/2002	REQUEST FOR EXTENSION OF TIME - GRANTED			
15	06/06/2002	MAIL NON-FINAL REJECTION			
14	06/06/2002	NON-FINAL REJECTION			
13		DATE FORWARDED TO EXAMINER			
12	03/28/2002	RESPONSE TO ELECTION / RESTRICTION FILED			
11	03/28/2002	REQUEST FOR EXTENSION OF TIME - GRANTED			
10	01/31/2002	MAIL RESTRICTION REQUIREMENT	10		-1
9	01/31/2002	REQUIREMENT FOR RESTRICTION / ELECTION			
8	06/29/2001	CASE DOCKETED TO EXAMINER IN GAU			
7	06/13/2001	APPLICATION DISPATCHED FROM OIPE			
6	06/13/2001	APPLICATION IS NOW COMPLETE			
5	03/29/2001	NOTICE MAILEDAPPLICATION INCOMPLETE FILING DATE ASSIGNED			
4	03/29/2001	CORRESPONDENCE ADDRESS CHANGE			
3	03/29/2001	CORRESPONDENCE ADDRESS CHANGE			
2	12/19/2000	IFW SCAN & PACR AUTO SECURITY REVIEW			
1	11/21/2000	INITIAL EXAM TEAM NN		<u></u>	

Search Another: Application#

EXPLANATION OF PTA CALCULATION

EXPLANATION OF PTE CALCULATION

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Back to PALM | ASSIGNMENT | OASIS | Home page

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Home | Site Index | Search | FAQ | Glossary | Guides | Contacts | eBusiness | eBiz Alerts | News | Help

FORMULATIONS FOR PHARMACEUTICAL AGENTS IONIZABLE AS FREE ACIDS OR Order Certified Application As Fil-Applicant Delay(APPL): 213 USPTO Delay (PTO): 508 Total PTA: 295 Order Certified File Wrapper Three Years: **Explanation Of Calculations** Patent Term Adjustment (PTA) for Application Number: 09/716,332 View Order List Patent Term Adjustment History Issue Date of Patent: 04-12-2005 Filing or 371(c) Date: 11-21-2000 Dele 9 Pre-Issue Petitions (days): +0 USPTO Adjustment(days): | +0 Post-Issue Petitions (days): nage File | Patent Term Wrapper | Adjustments **Enter Number:** Patent Application Information Retrieval BASES Application Number 🔽 Histony Select Search 09/716,332 Method: **Trademarks** 0 Supplemental Resources & Support Patent Application Information Patent Guidance and General Info Search Patents & Applications Employee & Office Directories Search Biological Sequences Copies, Products & Services Resources & Public Notices **Patents** Codes, Rules & Manuals Patent Official Gazette Patent Information Patent eBusiness **Electronic Filing** Patent Searches Copyrights Trademarks Policy & Law Portal Home Fees Reports Other (PAIR) \oplus $\pm \pm$ + \oplus \oplus

PTO(Days) APPL(Days

236

Patent Issue Date Used in PTA Calculation

Receipt into Pubs

02-17-2005 02-17-2005

03-23-2005

PTA 36 Months

04-12-2005

Date

Dispatch to FDC

02-17-2005

Contents Description

Application Is Considered Ready for Issue Response to Amendment under Rule 312

Petition Decision - Dismissed

02-17-2005 **02-08-2005**

06-10-2004

Receipt into Pubs

03-24-2004	Issue Fee Payment Verified	*	
Т	Petition Entered	4	ll
03-24-2004	Amendment after Notice of Allowance (Rule 312)	4	12
03-24-2004	Issue Fee Payment Received	\(احا
03-22-2004	Receipt into Pubs	4	٦
03-19-2004	Workflow - File Sent to Contractor	4	_
12-24-2003	Mail Notice of Allowance	4	
12-24-2003	Mail Examiner's Amendment	4	۲
12-22-2003	Notice of Allowance Data Verification Completed	4	~
12-22-2003	Case Docketed to Examiner in GAU	\(\psi\	ا ۲
12-22-2003	Examiner's Amendment Communication	Φ	~
11-07-2003	IFW Amended case processing Complete	Ψ	ا ۲
11-07-2003	Date Forwarded to Examiner	\P	٦
10-20-2003	Response after Non-Final Action	\P	``
07-18-2003	Mail Non-Final Rejection	4	٦
07-18-2003	Non-Final Rejection	4	
07-10-2003	Date Forwarded to Examiner	\P	
06-19-2003	Amendment after Final Rejection	4	
03-19-2003	Mail Final Rejection (PTOL - 326)	\(\psi\	
03-19-2003	Final Rejection	4	
01-08-2003	Date Forwarded to Examiner	\(\phi\)	
12-06-2002	Response after Non-Final Action	4	თ
12-06-2002	Request for Extension of Time - Granted	4	۲
06-06-2002	Mail Non-Final Rejection	•	~
06-06-2002	Non-Final Rejection	Ψ	
04-08-2002	Date Forwarded to Examiner	Φ	
03-28-2002	Response to Election / Restriction Filed	•	1
03-28-2002	Request for Extension of Time - Granted	4	ı
01-31-2002	Mail Restriction Requirement	10	
01-31-2002	Requirement for Restriction / Election	Ψ	
06-29-2001	Case Docketed to Examiner in GAU	4	
06-13-2001	Application Dispatched from OIPE	Φ.	
06-13-2001	Application Is Now Complete	\	ı
03-29-2001	Notice MailedApplication IncompleteFiling Date Assigned	\(\big 	
03-29-2001	Correspondence Address Change	Ψ	l
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	03-29-2001	12-19-2000	11-21-2000

If you need help:

- Call the Patent Electronic Business Center at (866) 217-9197 (toll free) or e-mail EBC@uspto.gov for questions about Patent Application Information Retrieval (PAIR).
- Send general questions about USPTO programs to the <u>USPTO Contact Center (UCC)</u>.
 If you experience technical difficulties or problems with this application, please report them via e-management or call 1 800-786-9199.

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FOLEY & LARDNER LLP ATTORNEYS AT LAW

IN THE US PATENT AND TRADEMARK OFFICE

Receipt is hereby acknowledged of the following:

Applicant:

Narmada SHENOY et al.

Serial No.:

09/716,332

Docket No. 034536-0155

Filing Date:

November 21, 2000

Formulations for Pharmaceutical Agents Ionizable as Free Acids or Free Bases For:

Issue Fee Transmittal (2 pp.); 1.

PTOL-85 (1 p.) (in duplicate); 2.

Request for Reconsideration of Patent Term Adjustment 3.

Check No. 34004 in the amount of \$1330.00; and 4.

Check No. 34005 in the amount of \$200.00. 5.

File in Mailroom
Date Filed: March 24, 2004

Due Date: March 24, 2004

Return To: BAB/mdm Inspected by:

United States Patent and Trademark Office

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FORMULATIONS FOR PHARMACEUTICAL AGENTS IONIZABLE AS FREE ACIDS OR BASES Start Dow This application is officially maintained in electronic form. To View: Click the desired Document Description. T Print: Check the desired document(s) and click StartDownload. **©** Order Certified Application As Fil-Order Certified File Wrapper Address & Attorney/Agent Select All View Order List Page Count 3 ന S Fees Published Documents Petition for review and processing by the Petition for review and processing by the **Miscellaneous Internal Document** Continuity Data Issue Fee Payment Recorded Document Description n Transaction Image File Patent Term **Petition Decision** Office of Petitions. Office of Petitions. Petition Decision **Enter Number:** - 🗆 Patent Application Information Retrieval Application Number 🔄 Select Search 02-08-2005 01-23-2006 04-27-2005 04-27-2005 03-24-2004 03-24-2004 09/716,332 \pplication Data Method: **Trademarks** Supplemental Resources & Support Patent Application Information Patent Guidance and General Info E Search Patents & Applications **Employee & Office Directories** Search Biological Sequences ☐ Copies, Products & Services Resources & Public Notices **Patents** Codes, Rules & Manuals Patent Official Gazette ← Patent Ownership Patent Information Patent eBusiness Electronic Filing Patent Searches Copyrights Trademarks Policy & Law Portal Home Reports Fees (PAIR) Other \oplus \pm \pm + \oplus \oplus \pm

12-24-2003	Notice of Allowance and Fees Due (PTOL-85)	က	
12-24-2003	Notice of Allowance and Fees Due (PTOL-85)	ည	П
12-24-2003	Examiner Interview Summary Record (PTOL - 413)	2	
12-24-2003	<u>List of References cited by applicant and considered by examiner</u>	ω	
12-24-2003	Issue Information including classification, examiner, name, claim, renumbering, etc.	7-	, , , , , , , , , , , , , , , , , , ,
12-24-2003	Search information including classification, databases and other search related notes	-	
12-04-2003	Examiner's search strategy and results	2	
10-20-2003	Amendment - After Non-Final Rejection	_	
10-20-2003	Claims	14	
10-20-2003	Applicant Arguments or Remarks Made in an Amendment	ю	
07-18-2003	Non-Final Rejection	9	П
07-18-2003	Examiner's search strategy and results	2	
06-19-2003	Power of Attorney (may include Associate POA)	7	
06-19-2003	Amendment - After Non-Final Rejection	-	
06-19-2003	Claims	ĸ	П
06-19-2003	Applicant Arguments or Remarks Made in an Amendment	7	
03-19-2003	Non-Final Rejection	œ	
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	Amendment - After Non-Final Rejection	-	
	<u>ms</u>	8	
·	Applicant Arguments or Remarks Made in an Amendment	12	
06-06-2002 Non	Non-Final Rejection	7	
06-06-2002 List	List of references cited by examiner	~	
06-05-2002 Exar	Examiner's search strategy and results		
04-30-2002 Exa	Examiner's search strategy and results	446	
03-28-2002 Exte	Extension of Time	-	
03-28-2002 Am	Amendment - After Non-Final Rejection	2	
01-31-2002 Reg	Requirement for Restriction/Election	5	
08-31-2001 NPL	NPL Documents	ത	
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08-31-2001	NPL Documents	2	
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08-31-2001	NPL Documents	12	
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08-31-2001	NPL Documents	8	
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08-31-2001	NPL Documents	12	
08-31-2001	NPL Documents	4	
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NPL Documents 7 NPL Documents 9 NPL Documents 8	08-31-2001	NPL Documents	4	
NPL Documents 9 NPL Documents 8 NPL Documents 8	08-31-2001	NPL Documents	7	
NPL Documents 8 8 INPL Documents 8 8 INPL Documents 8 INP	08-31-2001	NPL Documents	12	
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08-31-2001	NPL Documents	9	
08-31-2001	NPL Documents	14	
08-31-2001	NPL Documents	1	
08-31-2001	NPL Documents	7	
08-31-2001	NPL Documents	1	
08-31-2001	NPL Documents	2	
08-31-2001	NPL Documents	12	
08-31-2001	NPL Documents	7	
08-31-2001	NPL Documents	5	
08-31-2001	NPL Documents	7	
08-31-2001	NPL Documents	5	
08-31-2001	Foreign Reference	54	
08-31-2001	Foreign Reference	9	
08-31-2001	Foreign Reference	16	
08-31-2001	Foreign Reference	12	
08-31-2001	Foreign Reference	22	
08-31-2001	Foreign Reference	[
08-31-2001	Foreign Reference	95	
08-31-2001	Foreign Reference	20	
08-31-2001	Foreign Reference	149	
08-31-2001	Foreign Reference	240	

08-31-2001	Foreign Reference	246	
08-31-2001	Foreign Reference	170	
08-31-2001	Foreign Reference	148	
08-31-2001	Foreign Reference	64	
08-31-2001	Foreign Reference	366	
08-31-2001	Foreign Reference	352	
08-31-2001	Foreign Reference	512	
08-31-2001	Foreign Reference	156	П
08-31-2001	Foreign Reference	412	П
08-31-2001	Foreign Reference	64	
08-31-2001	Foreign Reference	58	П
08-31-2001	Foreign Reference	122	
08-31-2001	Foreign Reference	09	
08-31-2001	Foreign Reference	92	
08-31-2001	Foreign Reference	54	
08-31-2001	Foreign Reference	80	П
08-31-2001	Foreign Reference	269	
08-31-2001	Foreign Reference	69	
08-31-2001	Foreign Reference	40	
08-31-2001	Foreign Reference	63	□ [′]
08-31-2001	Foreign Reference	116	

08-31-2001	Foreign Reference	145	П
08-31-2001	Information Disclosure Statement (IDS)	10	
08-31-2001	Foreign Reference	42	Ц
08-31-2001	Foreign Reference	27	
08-31-2001	Foreign Reference	19	
08-31-2001	Foreign Reference	62	
08-31-2001	Foreign Reference	64	
08-31-2001	Foreign Reference	34	П
08-31-2001	Foreign Reference	213	П
08-31-2001	Foreign Reference	41	П
05-29-2001	Oath or Declaration filed	4	
05-29-2001	Miscellaneous Incoming Letter	m	
03-29-2001	Miscellaneous Action with SSP		П
11-21-2000	Issue Information including classification, examiner, name, claim, renumbering, etc.	-	
11-21-2000	Index of Claims	~	
11-21-2000	Search information including classification, databases and other search related notes	-	
11-21-2000	Transmittal letter	2	Ц
11-21-2000	Specification	234	
11-21-2000	Claims	4	П

11-21-2000	Abstract	-	П
11-21-2000	Oath or Declaration filed	4	
11-21-2000	Claims Worksheet (PTO-2022)	-	
11-21-2000	Fee Worksheet (PTO-875)	-	
11-21-2000	Miscellaneous Incoming Letter	255	
11-21-2000	Miscellaneous Incoming Letter	255	

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03-24-2004	Issue Fee Payment Received
03-22-2004	Receipt into Pubs
03-19-2004	Workflow - File Sent to Contractor
12-24-2003	Mail Notice of Allowance
12-24-2003	Mail Examiner's Amendment
12-22-2003	Notice of Allowance Data Verification Completed
12-22-2003	Case Docketed to Examiner in GAU
12-22-2003	Examiner's Amendment Communication
11-07-2003	IFW Amended case processing Complete
11-07-2003	Date Forwarded to Examiner
10-20-2003	Response after Non-Final Action
07-18-2003	Mail Non-Final Rejection
07-18-2003	Non-Final Rejection
07-10-2003	Date Forwarded to Examiner
06-19-2003	Amendment after Final Rejection
03-19-2003	Mail Final Rejection (PTOL - 326)
03-19-2003	Final Rejection
01-08-2003	Date Forwarded to Examiner
12-06-2002	Response after Non-Final Action
12-06-2002	Request for Extension of Time - Granted
06-06-2002	Mail Non-Final Rejection
06-06-2002	Non-Final Rejection
04-08-2002	Date Forwarded to Examiner
03-28-2002	Response to Election / Restriction Filed
03-28-2002	Request for Extension of Time - Granted
01-31-2002	Mail Restriction Requirement
01-31-2002	Requirement for Restriction / Election
06-29-2001	Case Docketed to Examiner in GAU
06-13-2001	Application Dispatched from OIPE
06-13-2001	Application Is Now Complete
03-29-2001	Notice MailedApplication IncompleteFiling Date Assigned

03-29-2001	Correspondence Address Change
03-29-2001	Correspondence Address Change
12-19-2000	IFW Scan & PACR Auto Security Review
11-21-2000	11-21-2000 Initial Exam Team nn

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